IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	**Case #: 3:05-00444**
	)	**Judge Trauger**
Plaintiff,	)	
-against-	)	
PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC and JOHN DOE(S) 1-10,	)	
Defendants.	)	

PLAINTIFF'S RESPONSE TO DEFENDANTS' OBJECTIONS TO THE PROPOSED STATEMENT OF PLAINTIFF'S EXPERT CHARLES KING, III, PH.D.

Plaintiff Ruth Smith, as the Widow for the use and benefit of herself and the next of kin of Richard Smith, deceased, by and through her attorneys, hereby submits Plaintiff's Response to Defendants' Objections to the Proposed Statement of Plaintiff's Expert Charles King, III, Ph.D.

Testimony	Objection	Response
All of fourth ¶ on page 11 – "A study published by Dr. Catherine Fullerton and others . . ."	• Testimony discusses study not disclosed or discussed in Dr. King's expert report or reliance disclosure. (FRCP 26(a)(2)(B).)	Study was disclosed on April 12, as soon as study was published and made known to expert. Fromson disclosure attached to earlier email
First and fifth bulleted ¶¶ on page 2; fourth bulleted ¶ on Slides 1 and 13.	• Dr. King's statements about alleged "suppression" of information on the adverse effects of Neurontin lack foundation, and exceed the scope of Dr. King's expertise as an economist. Dr. King is not qualified to determine the "adverse effects" of Neurontin and is therefore not unqualified to opine whether such adverse effects were "suppressed." (FRE 702/703.)	Dr. King does not 'determine' the adverse effects but merely accepts as true the admissions in defendants records, identified in his expert report, that such negative outcomes to trials and adverse effects were as reported and, as reported, were delayed or not disclosed. The defendants' records are the foundation for whether such effects were negative or adverse and are unequivocal that information about the effects of Neurontin was suppressed or delayed from disclosure to the public. See his report, page 37, paragraph 62, and documents referenced therein: "Another example of a negative study that was delayed by Pfizer is the POPP study. See Pfizer_JMarino_0000703-4, Pfizer_JMarino_0000809, and Pfizer_RGlanzman_0134501-3." "From E-mail of John Marino, Pfizer Neurontin World Wide Team Leader: "We must delay the publication of -224, as its result were not positive (*sic*)." Pfizer_LCastro_0002678-82, at Pfizer_LCastro_0002680. See also, Pfizer_JMarino_0000809,Pfizer_LeslieTive_0020985-6 and Pfizer_LeslieTive_0080783-4." Dr. King is qualified by training and experience as a marketing analyst for pharmaceutical products to observe and form opinions on whether information was suppressed and the effects on the market of such suppression of information.

Testimony	Objection	Response
Slide 3; Second ¶ on page 3 – "This fact was evident to Warner-Lambert. By 1995, Warner-Lambert had analyzed the prospects for Neurontin if marketed only for approved uses and estimated its lifetime future sales would add up to only $500 million. While $500 million seems like a lot of money, it is only a fraction of the total amount of sales actually generated by Neurontin".	• Reference to original estimate for lifetime Neutontin market is irrelevant, misleading and unfairly prejudicial because the referenced estimate is based on epilepsy use only, and Neurontin received FDA approval for PHN, a type of neuropathic pain, after the original estimate. (FRE 402/403)	Comparisons of defendants' economic forecast for legal sales of its product to the actual sales realized after seven – plus years of admittedly illegal promotion is a legitimate economic observation of the success of illegal promotion. It is relevant to whether the promotion succeeded in obtaining off-label prescriptions, to economic incentive and motive to pursue off-label prescriptions. Defendant may cross-examine if defendant contends it is confusing or misleading.

Testimony	Objection	Response
First ¶ under bulleted list on page 4 – "To settle these criminal charges, Warner-Lambert paid a total of $430 million in criminal fines and reimbursements. Again, $430 million sounds like a lot of money, but it was only a small fraction of the total amount of Neurontin sales that resulted from their illegal off-label marketing activities."	• Dr. King's commentary on penalties paid by Pfizer is irrelevant to any opinion properly stated in Dr. King's statement, and represents legal testimony outside Dr. King's area of expertise. (FRE 402/702)	Comparisons of defendants' penalties for admittedly illegal sales of its product to the actual sales realized after seven – plus years of admittedly illegal promotion is a legitimate economic observation of the success of illegal promotion. It is relevant to whether the promotion succeeded in obtaining off-label prescriptions, to economic incentive and motive to pursue off-label prescriptions. The numbers are not legal opinions but are factual admissions by defendants of one measure of the extent of their illegal promotion. Defendant may cross-examine if defendant contends it is confusing or misleading.

Testimony	Objection	Response
First two full sentences at top of page 7 – "In the years following Neurontin's initial approval, Warner-Lambert and Pfizer implemented strategies to promote Neurontin for a variety of off-label uses including pain, psychiatric disorders and at doses of more than 1800 mg per day. In each case, off-label Neurontin prescriptions sharply increased after the commencement of off-label marketing campaigns. These strategies included drug company representatives, medical liaisons, and continuing medical education events."	• Discussion of promotion for off-label uses other than the one at issue in this case—neuropathic pain—is irrelevant to any issue related to Mr. Smith's use of Neurontin, or to any alleged duty for Pfizer to test or warn about use of Neurontin in patients with Neuropathic pain. Such testimony is also unfairly prejudicial and likely to confuse the jury concerning the facts at issue in this case. (FRE 402/403)	Defendants' promotion for off-label uses was always for multiple indications, never just one indication such as Neuropathic pain. The slide decks used by sales representatives listed some twelve indications in a single presentation. See, for example, Exhibit 2020 (Franklin disclosures), page Relator 386, which lists on a single promotion page 13 different illnesses that Neurontin supposedly cures, including four kinds of pain, several kinds of psychiatric illnesses, and various dystrophies and neuralgias. The sales representatives were told to promote for multiple indications, based on the tape recorded statements made to Dr. Franklin. The publication planning for off-label indications allocated budgets and articles for multiple indications. The CME sponsored by defendants for off-label promotion was for multiple 'emerging uses.' Defendant may cross-examine if defendant contends it is confusing or misleading.

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First 2 ¶s at top of page 8 – " Warner- Lambert sales representatives encouraged doctors to prescribe Neurontin for a variety of off-label uses ***even when there was no evidence to support claims of effectiveness or when studies had shown that the drug was not effective***." (emphasis added)	• Statement concerning medical and scientific evidence as to Neurontin's efficacy lies outside Dr. King's expertise as an economist. (FRE 702) • Broad and non-specific statement is irrelevant and unfairly prejudicial. (FRE 402/403)	Dr. King does not 'determine' the adverse effects but merely accepts as true the admissions in defendants records, identified in his expert report, that such negative outcomes to trials and adverse effects were as reported and, as reported, were delayed or not disclosed. The defendants' records are the foundation for whether such effects were negative or adverse and are unequivocal that information about the effects of Neurontin was suppressed or delayed from disclosure to the public. Dr. King is qualified by training and experience as a marketing analyst for pharmaceutical products to observe and form opinions on whether information was suppressed and the effects on the market of such suppression of information. He may rely on the scientific observations of others, including defendants, as a part of his analysis and observations.

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Slide 10 and Third ¶ on page 8 – "**[Slide 10]** Company documents show that they targeted psychiatrists, who typically would have no reason to use Neurontin for its approved uses."	• Discussion of promotion to psychiatrists is irrelevant to any issue related to Mr. Smith's use of Neurontin, or to any alleged duty for Pfizer to test or warn about use of Neurontin in patients with Neuropathic pain. Such testimony is also unfairly prejudicial and likely to confuse the jury concerning the facts at issue in this case. (FRE 402/403)	This evidence contradicts Pfizer's contention that it did not improperly promote Neurontin after acquiring Warner-Lambert in 2000. In addition, Defendants' promotion for off-label uses was always for multiple indications, never just one indication such as Neuropathic pain. Pain and psychiatric indications were frequently promoted jointly. The slide decks used by sales representatives listed some twelve indications in a single presentation. See, for example, Exhibit 2020 (Franklin disclosures), page Relator 386, which lists on a single promotion page 13 different illnesses that Neurontin supposedly cures, including four kinds of pain, several kinds of psychiatric illnesses, and various dystrophies and neuralgias. The sales representatives were told to promote for multiple indications, based on the tape recorded statements made to Dr. Franklin. The publication planning for off-label indications allocated budgets and articles for multiple indications. The CME sponsored by defendants for off-label promotion was for multiple 'emerging uses.' Defendant may cross-examine if defendant contends it is confusing or misleading.

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Slide 11	• No objection, but Pfizer requests a limiting instruction that the sponsorship of Continuing Medical Education events by pharmaceutical companies was and is a safe harbor and protected activity under the FDA regulations. They do not constitute promotion and was an acceptable vehicle to disseminate information about the offlabel uses of drugs to physicians outside of a "selling" context.	Defendant judicially admitted in the guilty plea and plea agreement to the criminal information that its sponsorship of CME for off-label promotion was illegal and, accordingly, it is not entitled to safe harbor status.

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Second ¶ on page 10 – "Pfizer, like Warner- Lambert, had strong economic incentives to continue promoting off-label uses of Neurontin . . . ."	• Dr. King's statements about alleged "suppression" of information on the adverse effects of Neurontin lack foundation, and exceed the scope of Dr. King's expertise as an economist. Dr. King is not qualified to determine the "adverse events" of Neurontin and is therefore not unqualified to opine whether such adverse effects were "suppressed." (FRE 702/703.)	Judge Saris specifically declared that marketing incentives for illegal promotion is relevant and admissible in denying Defendants' motion to exclude evidence of marketing by defendants of Neurontin. From the pretrial hearing of July 20, 2009: 13 25 THE COURT: All right, a few things: The plaintiffs will be allowed to introduce evidence about a national marketing campaign. That is relevant to not only the issue of intent -- is fraud still part of this, intentional -- 5 MR. FROMSON: Yes, your Honor. 6 MR. FINKELSTEIN: Yes. 7 THE COURT: -- as well as the duty to understand that this was being nationally marketed for off-label in areas that were not just epilepsy. I think that's very important, and I think the probative value substantially outweighs the prejudicial value. 12 MR. CHEFFO: Your Honor, may I just - 13 THE COURT: Yes. 14 MR. CHEFFO: They answered "yes" very quickly, but your order on the fraud, this is, I think -- 16 THE COURT: It's fraud by omission. 17 MR. CHEFFO: That's correct, but what your Honor did say was, "The motions to dismiss the fraudulent concealment claims are denied in all the complaints, except to the extent that they are premised on the claim of fraudulent omissions in the national advertising and marketing campaign." So it's our position, your Honor, that you did rule on that with respect to national marketing. And I would also just add -- 25 THE COURT: It goes to corporate intent, the profit motive, why you would have an intent not to disclose certain things, as well as the extent of the information that you had available, you knew that it was being marketed off-label. 5 MR. CHEFFO: But, see, the issue -- 6 THE COURT: Denied, denied. Market incentives are legitimate economic measures of the viability and existence of product promotion, including illegal promotion. It is relevant to whether the promotion succeeded in obtaining off-label prescriptions, to economic incentive and motive to pursue off-label prescriptions. Dr. King does not 'determine' the adverse effects but merely accepts as true the admissions in defendants records, identified in his expert report, that such negative outcomes to trials and adverse effects were as

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Portions of ¶ 2, all of ¶ 3 and portion of ¶ 4 on page 13 – "John Marino, Pfizer's Worldwide Team Leader for Neurontin, testified in his deposition before this trial began, that Pfizer has an obligation to share negative results of its exploratory studies with the medical community and that this was the practice at both Warner-Lambert and Pfizer. To suppress or delay a negative study would be misleading and would not present a fair and balanced view, according to Mr. Marino. "The pharmaceutical company's responsibility is to help teach physicians about the risk/benefit profile of appropriate therapies for treatment," including a full explanation of what the risks are, Mr. Marino further testified. Yet Pfizer allegedly took no affirmative action to disclose what it knew about	• Improper "narrative" testimony absent personal knowledge, which simply recites facts without reference to any proper expert opinion or analysis, and is not reasonably tailored to explain the basis for any qualified opinion being offered. (FRE 602, 703.) • Testimony concerning allegations about efficacy in relation to bipolar disorder or use by psychiatrists are irrelevant to the prescription and use by Mr. Smith and unfairly prejudicial. (FRE 402/403)	• Admissions by defendants' Worldwide Team Leader of recognition of a duty to disclose negative information are factual observations upon which an expert may rely in analyzing whether such a failure to disclose was reasonable or was a contributing factor to the success of a marketing program. This observation was appropriate, based on scholarly studies relied on by Dr. King, identified in his report and supplemental Rule 26 disclosures. See report, page 50, Paragraph 95, and scholarly studies he incorporated on the adverse effects of negative studies and risks on drug sales: "*See, e.g.*, Ernst R. Berndt, Linda Bui, David R. Reiley and Glen Urban, "Information, Marketing, and Pricing in the U.S. Antiulcer Drug Market," *American Economic Review* (1995), 85, 2, 100-105; E.R. Berndt, A. Bhattacharja, D.N. Mishol, A. Arcelus and T. Lasky, "An Analysis of the Diffusion of New Antidepressants: Variety, Quality, and Marketing Efforts," *Journal of Mental Health Policy and Economics* (2002), 5, 3-19 ("[P]roduct quality – but particularly a more favorable side effect profile – has a very substantial impact on product market share." p. 17)" • The testimony is not about efficacy but is, instead, testimony about Defendants' suppression of evidence of a lack of efficacy. That such suppression of evidence included psychiatric indications as well as pain indications is evidence of Defendants' broad plan to withhold from doctors information that would have led to reduction in sales. This is supported by the scholarly studies identified by Dr. King in his expert report, set out in the preceding response (part A).

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First sentence in second full ¶ on page 14 – "Doctors would consider this information material to their decisions to prescribe _eurontin and it would have affected their behavior	• This statement is vague and ambiguous as to whether the referenced "doctors" are the particular physicians who prescribed Neurontin for Mr. Smith. To the extent it refers to doctors other than Dr. Mackey, the prescribing doctor in this case, the statement is irrelevant. To the extent it refers to Dr. Mackey, the statement is speculative, and is not the proper subject of expert testimony, particularly given that Dr. Mackey has provided deposition testimony, and may appear at trial. As stated, the sentence if likely to confuse and mislead the jury as to the proper questions at issue relating to Plaintiff's inadequate	Defendant may cross examine both Dr. King and Dr. Mackey. Dr. King, as set out in his expert report, observed that there are multiple factors which lead to prescription decisions, including but not limited to information presented by sales representatives, information shared between peers, and information published in literature. Each factor may be a material consideration. The scholarly studies identified by Dr. King in his report establish that prescribing doctors are rarely aware of all factors that lead to prescription decisions. See Report page 45 et seq, paragraphs 83-85, and referenced studies: Dale D. Christiansen and Albert J. Wertheimer (1979), "Sources of Information and Influence upon New Drug Prescribing among Physicians in an HMO," Soc. Sci. & Med., pages 313-322; Harikresh Nair, Puneet Manchanda, Tulidaa Bhatia, "Asymmetric Peer Effects in Physician Prescription Behavior: The Role of Opinion Leaders," Stanford Working Paper.

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Second sentence in second full ¶ on page 14 – "I understand that although the mode of action of Neurontin was unknown when the drug was originally approved, it is now known that Neurontin depletes serotonin and neuropinephrine and that low levels of these neurotransmitters are an established risk factor for depression and suicide."	• Dr. King's comments on the neurochemical properties of Neurontin represent unqualified opinions about the safety and efficacy of Neurontin, the meaning or significance of particular research findings or studies about Neurontin, or the propriety of medical research or publication practices. (FRE 702.)	An expert may rely on the observations of others if of the type reasonably relied on by others in the field. This includes observations by Defendant and its employee – expert Dr. Taylor that the mechanism of action of Neurontin was not known when originally approved but is now known and observations by Dr. Trimble and others that reduced levels of serotonin are risk factors. Rule 703-704.

Testimony	Objection	Response
Slide 13 and First sentence in first full ¶ on page 15 – "Thus suppression of adverse information about Neurontin further enabled Neurontin off-label sales. **[Slide 13]"**	• Dr. King's statements about alleged "suppression" of information on the adverse effects of Neurontin lack foundation, and exceed the scope of Dr. King's expertise as an economist. Dr. King is not qualified to determine the "adverse effects" of Neurontin and is therefore not unqualified to opine whether such adverse effects were "suppressed." (FRE 702/703.)	Dr. King does not 'determine' the adverse effects but merely accepts as true the admissions in defendants records, identified in his expert report, that such negative outcomes to trials and adverse effects were as reported and, as reported, were delayed or not disclosed. The defendants' records are the foundation for whether such effects were negative or adverse and are unequivocal that information about the effects of Neurontin was suppressed or delayed from disclosure to the public. See his report, page 37, paragraph 62, and documents referenced therein: "Another example of a negative study that was delayed by Pfizer is the POPP study. See Pfizer_JMarino_0000703-4, Pfizer_JMarino_0000809, and Pfizer_RGlanzman_0134501-3." "From E-mail of John Marino, Pfizer Neurontin World Wide Team Leader: "We must delay the publication of -224, as its result were not positive (*sic*)." Pfizer_LCastro_0002678-82, at Pfizer_LCastro_0002680. See also, Pfizer_JMarino_0000809,Pfizer_LeslieTive_0020985-6 and Pfizer_LeslieTive_0080783-4." Dr. King is qualified by training and experience as a marketing analyst for pharmaceutical products to observe and form opinions on whether information was suppressed and the effects on the market of such suppression of information.

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Page 1, Third bullet; Page 2, fourth bullet, Slide 1, third bullet, and similar testimony about the "effects" of off-label promotion on "all or substantially all" physicians.	• Improper expert opinion that is unsupported by any foundation or quantitative analysis and invites jury speculation on the cause of Mr. Smith's physician to prescribe Neurontin to Mr. Smith. (FRE 702/402/403)	Defendant may cross examine both Dr. King and Dr. Mackey. Dr. King, as set out in his expert report, observed that there are multiple factors which lead to prescription decisions, including but not limited to information presented by sales representatives, information shared between peers, and information published in literature. Each factor may be a material consideration. The scholarly studies identified by Dr. King in his report establish that prescribing doctors are rarely aware of all factors that lead to prescription decisions. See Report page 45 et seq, paragraphs 83-85, and referenced studies: Dale D. Christiansen and Albert J. Wertheimer (1979), "Sources of Information and Influence upon New Drug Prescribing among Physicians in an HMO," Soc. Sci. & Med., pages 313-322; Harikresh Nair, Puneet Manchanda, Tulidaa Bhatia, "Asymmetric Peer Effects in Physician Prescription Behavior: The Role of Opinion Leaders," Stanford Working Paper.

Dated: May 13, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 13th day of May, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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